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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/808,411	03/25/2004	Toshihiro Mori	0649-0994PUS1	5118
2292 7590 07/30/2008 BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747				
EXAMINER LU, FRANK WEI MIN				
ART UNIT 1634		PAPER NUMBER		
NOTIFICATION DATE 07/30/2008		DELIVERY MODE ELECTRONIC		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary

Application No.

10/808,411

Applicant(s)

MORI ET AL.

Examiner

FRANK W. LU

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 February 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 and 34-36 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-15, 19-23, and 34-36 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 3/25/2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/808)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. In view of applicant's amendment filed on February 27, 2008 and newly found rejections summarized herein, **PROSECUTION IS HEREBY REOPENED**. New ground of rejection are set forth below, the finality of the action mailed on December 4, 2007 is withdrawn. The claims pending in this application are claims 1-23 and 34-36 wherein 16-18 has been withdrawn due to species election mailed on January 22, 2007. Rejection and/or objection not reiterated from the previous office action are hereby withdrawn. Claims 1-15, 19-23, and 34-36 will be examined.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-15, 19-23, and 34-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 1 or 11 is rejected as vague and indefinite because it is unclear that an operation part of a piston member is inside of the syringe or not. Please clarify.

5. Claim 5 is rejected as vague and indefinite. Since claim 1 does not require that a solid phase-holding member is a column with a circular shape, it is unclear why a circular solid phase-supporting surface can be formed on the inner surface of the leading end side of said solid phase-holding member, said solid phase that is formed in a circular shape can be placed in a direction parallel to said solid phase-supporting surface and the leading

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end of the leading end part of said syringe that is formed in a circular shape can be abutted to the immediate inside of the circular peripheral edge of said solid phase to press the solid phase to the side of said solid phase-supporting surface. Please clarify.

6. Claim 13 is rejected as vague and indefinite because it is unclear that an accommodation part is from the apparatus recited in claim 1 or not. Please clarify.

7. Claim 13 or 20 recites the limitation "the pressure change" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no phrase "pressure change" before "the pressure change" in the claim. Please clarify.

8. Claim 19 is rejected as vague and indefinite because it is unclear that a second opening part or an accommodation part in step (a) is from the apparatus recited in claim 1 or not. Please clarify.

9. Claim 20 is rejected as vague and indefinite because it is unclear which step in claim 19 is considered as next step. Please clarify.

10. Claim 23 or 35 or 36 recites the limitation "the container" in the claim. There is insufficient antecedent basis for this limitation in the claim because there is no word "container" before "the container" in the claim. Please clarify.

11. Claim 34 is rejected as vague and indefinite. Since claim 12 requires that adsorption and desorption of nucleic acids are performed using the apparatus recited in claim 1 while claim 34 requires that adsorption and desorption of nucleic acids are performed using an apparatus for separating and purifying nucleic acids comprising (a) a solid phase, (b) a container having at least two openings for accommodating said solid phase, (c) a pressure difference generating apparatus coupled to one of the openings of said container and (d) a pressure sensor and claim 34 is dependent on claim 12 and the

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apparatus recited in claims 12 and 34 are different, claims 12 and 34 do not correspond each other. Please clarify.

12. Claim 36 is rejected as vague and indefinite because it is unclear that a pressure sensor is from the apparatus recited in claim 1 or not. Please clarify.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

14. Claims 1, 5, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huse *et al.*, (US Patent No. 5,378,360, published on January 3, 1995) in view of Bach *et al.*, (US Patent No. 4,133,804, published on January 9, 1979) and Kojima *et al.*, (US Patent No. 6,179,569 B1, published on January 30, 2001).

Regarding claim 1 or 11, Huse *et al.*, teach a cylindrical syringe (i.e., syringe 90) having a leading end part in which a first opening part is formed, a base end part in which a second opening part is formed and an accommodation part between said first opening part and second opening part, the accommodation part being able to hold liquid therein; and a solid phase-holding member connected to said leading end part, a flow hole being formed at the leading end side of the solid phase-holding member; a solid phase comprised of an organic polymer (i.e., gel chromatography material such as polysaccharide) on the surface thereof is accommodated in said solid phase-holding member, the solid phase being able to adsorb and desorb nucleic acids in a sample solution; and wherein said piston member comprising a plunger (i.e., plunger 94) extending from said second opening part side into said accommodation part (see Figure 2 with the examiner's handwritings, columns 2 and 3, and claims 1 and 2).

Regarding claim 5, Huse *et al.*, teach that a circular solid phase-supporting surface is formed on the inner surface of the leading end side of said solid phase-holding member, the solid phase-supporting surface being generally perpendicular to the longitudinal axis of said syringe; said solid phase that is formed in a circular shape is placed in a direction parallel to said solid phase-supporting surface; the leading end of the leading end part of said syringe that is formed in a circular shape is abutted to the immediate inside of the circular peripheral edge of said solid phase to press the solid phase to the side of said solid phase-supporting surface (see Figure 2 with the examiner's handwritings, columns 2 and 3, and claims 1 and 2).

Huse *et al.*, do not disclose an organic polymer having a hydroxyl group and

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a pressure sensor capable of detecting the pressure in the accommodation part which is connected to an operation part of a piston member as recited in claim 1 or 11.

Bach *et al.*, teach an organic polymer having a hydroxyl group (ie., Sephadex) (see column 2, second paragraph).

Kojima *et al.*, teach that, in a syringe, a pressure sensor is arranged between said plunger receiving portion and the slider to detect a negative pressure applied to the plunger (see abstract and Figure 7).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made the apparatus recited in claim 1 or 11 comprising an organic polymer having a hydroxyl group and a pressure sensor capable of detecting the pressure in the accommodation part which is connected to an operation part of a piston member (ie., plunger) in view of the prior art of Huse *et al.*, Bach *et al.*, and Kojima *et al.*. One having ordinary skill in the art would have been motivated to do so because Sephadex is a commonly used separation resin comprising an organic polymer having a hydroxyl group (see Bach *et al.*, column 2, second paragraph) and is commercially available, and the addition of a pressure sensor to the syringe taught by Huse *et al.*, during the process for making the apparatus recited in claim 1 or 11 would provide a new feature for the apparatus taught by Huse *et al.*, so that one having ordinary skill in the art at the time the invention was made is capable of detecting the pressure in the accommodation part of the syringe. One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to make the apparatus recited in claim 1 in view of the prior art of Huse *et al.*, Bach *et al.*, and Kojima *et al.*.

15. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huse *et al.*, in view of Bach *et al.*, and Kojima *et al.*, as applied to claims 1, 5, and 11 above, further in view of Maroth (US Patent No. 3,811,442, published on May 21, 1974).

The teachings of Huse *et al.*, Bach *et al.*, and Kojima *et al.*, have been summarized previously, *supra*.

Huse *et al.*, Bach *et al.*, and Kojima *et al.*, do not disclose a liquid-tight member (ie., O-ring) provided at the leading end of said plunger wherein the liquid-tight member can be brought into close contact with the inner surface of said accommodation part and is slidable in said accommodation part as recited in claim 2.

Maroth teaches resilient O-ring adapted to slidably receive and frictionally grip and drive the syringe body. The resilient O-ring not only enables the syringe body to be fully inserted therein so as to be supported by the spaced-apart bearing portions of the casing, but it also bears against the syringe body in such a manner as to apply a turning force thereto when the motor is energized (see column 2).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have made an apparatus recited in claim 2 comprising a liquid-tight member (ie., O-ring) provided at the leading end of said plunger wherein the liquid-tight member can be brought into close contact with the inner surface of said accommodation part and is slidable in said accommodation part in view of the prior art of Huse *et al.*, Bach *et al.*, Kojima *et al.*, and Maroth. One having ordinary skill in the art would have been motivated to do so because Maroth suggests that “[T]he resilient O-ring not only enables the syringe body to be fully inserted therein so as to be

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supported by the spaced-apart bearing portions of the casing, but it also bears against the syringe body in such a manner as to apply a turning force thereto when the motor is energized" (see column 2). One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to make the apparatus recited in claim 2 in view of the prior art of Huse *et al.*, Bach *et al.*, Kojima *et al.*, and Maroth.

16. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Huse *et al.*, in view of Bach *et al.*, and Kojima *et al.*, as applied to claims 1, 5, and 11 above.

The teachings of Huse *et al.*, Bach *et al.*, and Kojima *et al.*, have been summarized previously, *supra*.

Huse *et al.*, Bach *et al.*, and Kojima *et al.*, do not disclose a method for separating and purifying nucleic acids which comprises adsorbing and desorbing nucleic acids in a sample solution on a solid phase comprised of an organic polymer having a hydroxyl group on the surface thereof by using the apparatus for separating and purifying nucleic acids according to claim 1. However, Huse *et al.*, teach a method for separating and purifying nucleic acids which comprises adsorbing and desorbing nucleic acids in a sample solution on a solid phase comprised of an organic polymer (see columns 3 and 4).

Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to have performed the method recited in claim 12 using the apparatus recited in claim 1 in view of the prior art of Huse *et al.*, Bach *et al.*, and Kojima *et al.*. One having ordinary skill in the art would have been motivated to do so because the apparatus recited in claim 1 is capable of being used for separating and purifying nucleic acids and separating and purifying nucleic acids is one of intended uses

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of the apparatus recited in claim 1. One having ordinary skill in the art at the time the invention was made would have a reasonable expectation of success to separate and purify nucleic acids using the apparatus recited in claim 1 in view of the prior art of Huse *et al.*, Bach *et al.*, and Kojima *et al.*.

Conclusion

17. No claim is allowed.

18. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

/Frank W Lu /
Primary Examiner, Art Unit 1634
June 10, 2008

